UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/485,473	02/11/00	STOFFEL W	P61950US1

EXAMINER	
CLEMENS,K	
ART UNIT	**PAPER NUMBER**
1644	6

HM12/0327

JACOBSON PRICE
HOLMAN & STERN
400 SEVENTH STREET NW
WASHINGTON DC 20004

DATE MAILED: 03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/485,473	Applicant(s) STOFFEL ET AL.	
	Examiner Karen Clemens	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2000* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☒ Other: *Notice to Comply with Sequence Rules* .

DETAILED ACTION

Election/Restrictions

1. This application contains sequence disclosures in the specification and the claims that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached "Notice To Comply With Requirements For Patent Applications Containing Nucleotide And/Or Amino Acid Sequence Disclosures."

Applicant's must provide an initial computer disk which includes the aforementioned nucleotide/amino acid sequences, a substitute paper copy of the "Sequence Listing" as well as an amendment directing its entry into the specification and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.821(d).

2. Groups V and VI encompass distinct products. A transgenic animal *overexpressing* the eukaryotic sphinogomyelinase differs from a transgenic animal *defective* in the expression of a eukaryotic sphinogomyelinase with respect to their mode of construction, structure and biological phenotype and a person of ordinary skill in the art would not envision one in view of the other.

Therefore, restriction has been set forth for each as a separate group, irrespective of the fact that they are recited within the same claim, since these transgenic animals lack a common mode of construction, structure and biological phenotype as required under PCT Rule 13.2.

3. For examination purposes, "use" claims are prosecuted as "methods of use" based on the first recited use. Additional uses recited within the "use" claim are considered intended uses and carry no patentable weight *per se*.

Applicant is reminded that such "use" claims are improper process claims and are subject to rejection under both 35 U.S.C. §101 and 35 U.S.C. §112, second paragraph.

4. Restriction is required under 35 U.S.C. §121 and 372:.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1, 2, 14 and 15, drawn to a eukaryotic neutral sphingomyelinase *protein* having the sequence of SEQ ID NO:1 or 2, a pharmaceutical composition (medicaments) and a diagnostic agent containing the protein.

II. Claim 20, drawn to a *method of producing the neutral sphingomyelinase protein* by chemical peptide synthesis.

III. Claims 3-8, 10, 11, 20, 23 and 24, drawn to a *nucleic acid* encoding a eukaryotic neutral sphingomyelinase having the sequence of SEQ ID NO:3 or 4, a gene for eukaryotic neutral sphingomyelinase, a cell line overexpressing neutral sphingomyelinase, a method (process) for producing the encoded eukaryotic neutral sphingomyelinase protein by expression in genetically engineered organisms, a method for producing the nucleic acid by amplification in genetically engineered organisms, and a pharmaceutical composition and a diagnostic agent containing the nucleic acid.

IV. Claim 21, drawn to a *method for producing the nucleic acid* encoding a eukaryotic neutral sphingomyelinase by chemical synthesis.

V. Claims 12 and 13 drawn to a *transgenic mammal overexpressing* the eukaryotic neutral sphingomyelinase.

VI. Claims 12 and 13 drawn to a *transgenic mammal with a deficiency or defect* in the expression of the eukaryotic neutral sphingomyelinase.

VII. Claims 16 and 17, drawn to a *method of treatment* (use of medicaments) using the eukaryotic neutral sphingomyelinase for diseases associated with the *increase* of expression or activity of eukaryotic neutral sphingomyelinase and/or, as they apply to the *increased* expression or activity, disorders of cell proliferation, cell differentiation and/or cell apoptosis.

VIII. Claims 16 and 17, drawn to a *method of treatment* (use of medicaments) using the eukaryotic neutral sphingomyelinase for diseases associated with the *decrease* of expression or activity of eukaryotic neutral sphingomyelinase and/or, as they apply to the *decreased* expression or activity, disorders of cell proliferation, cell differentiation and/or cell apoptosis.

IX. Claims 18-19, drawn to a *method for screening* for active substances that alter expression or activity of the eukaryotic neutral sphingomyelinase.

X. Claim 22, drawn to an *antibody directed against a nucleic acid* encoding the eukaryotic neutral sphingomyelinase.

XI. Claims 9, 25-26, drawn to a *pharmaceutical composition* (medicament) and a *diagnostic agent* containing an *antibody* directed against the eukaryotic neutral sphingomyelinase.

XII. Claim 27, drawn to a *method of diagnosing diseases* (use of diagnostic agents.. for the diagnosis of...) using the eukaryotic neutral sphingomyelinase for diseases associated with the increase or decrease of expression or activity of eukaryotic neutral sphingomyelinase and/or disorders of cell proliferation, cell differentiation and/or cell apoptosis.

5. The inventions listed as Groups I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

The inventions listed in Group I were found to have no special technical feature that defined the contribution over the prior art of Chatterjee et al. (*J. Biol. Chem.* 264:12554-12561, 1989, see IDS). Chatterjee et al. teach a eukaryotic neutral sphinomyelinase that is a variant of SEQ ID NO:1 or 2. Therefore the invention of Group I has been previously described.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and lack unity of invention.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to more than one *species* of the generic invention in Groups VII, VIII and XII. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is therefore required to elect a *specific species of disease* for the inventions of Groups VII, VIII and XII such as inflammation, cell growth disorders, cancer or a metabolic disorder.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The special technical feature of each species of disorder and therefore the basis of the disorder, is that they encompass distinct pathological conditions which differ in etiology and therapeutic endpoints.

9. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Currently claims 16, 17 and 27 are generic.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicants traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(l).

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Clemens whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Karen Clemens, Ph.D.
Patent Examiner
Technology Center 1600
March 23, 2001

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
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3/26/01